

# Declaration of Conformity

**Manufacturer:**  
WR Medical Electronics Co.

**Address:**  
123 North Second Street  
Stillwater, MN 55082-5047  
USA

**Product Group:** Baths, Paraffin, Physical Therapy

**Product Family:** Therabath® Pro® Professional Grade Paraffin Bath

**Device Name:** Therabath® Pro® TB4, TB5

**Product Part Number(s):** 2300, 2302, 2310, 2312, 2320, 2322, 2330, 2332, 2340, 2342, 2350, 2352

**Device Classification Per MDD:** Class IIa - per Rule 9

**Year of Manufacture:** 2003

**European Representative:** Medical Device Safety Service GmbH, Burckhardtstr 1, D-30163, Hannover, Germany

**Annex V Notified Body:** SEMKO (Sweden) (0413)

**Technical File No:** RA-1, Revision B, 9 February 2004

**Declaration:** WR Medical Electronics Co. hereby declares that the medical device specified above, to which this declaration relates, is in conformance with the essential requirements of Council Directive 93/42/EEC Medical Device Directive under Annex II (EC Declaration of Conformity; Production Quality Assurance), and with Swedish National Legislation under LVFS 2001:6.

**Declaration Based On:** Annex II of the Directive 93/42/EEC on Medical Devices

**Certificate No.:** 41314523

**Issued by:** Intertek SEMKO AB

**Declaration of Conformance Issued By:** Ms. Jeanne Anderson, Director of Regulatory and Clinical Affairs, Mr. Jack Blais, Executive Vice President, WR Medical Electronics Co. 123 North Second Street, Stillwater, MN 55082-5047 USA

**Prepared By:** Quality Steering Team and Director of Regulatory and Clinical Affairs

  
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(Ms. Jeanne Anderson)

  
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(Mr. Jack Blais)

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